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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT

PAPER NUMBER

1638

10

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n N .

09/811,050

Applicant(s)

STELPFLUG, DICK

Examiner

Medina A Ibrahim

Art Unit

1638

-- The MAILING DATE of this c mmunication appears on the cover sheet with the c rrespondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed on 09 April 2003, in reply to the Office action mailed 01/02/03. It is noted that the clean copy version of claim 19 is not provided. Applicant is required to provide the clean copy version of claim 19.

All previous rejections and objections not set forth below have been withdrawn.

Claims 1-20 are pending and are examined.

#### ***New Matter***

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

The claim recites additional step of " screening -----with biotechnology" techniques wherein identifying with genotyping that the seed is inbred". However, support for the phrases "biotechnology techniques" and "identifying with genotyping" cannot be found in pages 18-19 and 3-4 of specification or in the claims as originally filed. Therefore, the phrases are considered to be new matter. Applicant is requested to point to support for the phrases in the originally filed application or to delete the NEW MATTER in response to this rejection.

***Claim Rejections - 35 USC § 112***

1. Claims 5, 10-11, 14-17 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for the reasons of record as set forth in the Office action mailed 01/02/03. Applicant's arguments filed 04/09/03 have been fully considered but are not deemed persuasive.

Applicant argues that "capable of expressing" of claim 5 is not indefinite because the plant may not have all of the physiological and morphological characteristics of the inbred plant at all growing stages, i.e., from seed to mature plant, and then to senescence stage, however, the plant is capable of expressing such characteristics at some point. Applicant also argues that the word "having" does not address the issue of plant changing stages (response, page 1, 2<sup>nd</sup> full paragraph).

These arguments are not persuasive because the claim is directed to a regenerated corn plant rather than seed or a plant at senescence stage. A corn plant regenerated from the tissue culture of claim 4 is a mature corn plant and is expected to exhibit all the morphological and physiological characteristics of a mature plant of the inbred line G3001. The phrase, "capable of expressing" is indefinite because it is unclear when and under what conditions the claimed plant may express all the physiological and morphological characteristics of inbred line G3001.

Applicant argues that claims 15 and 16 are definite when read in light of the specification, and further argues that one skilled in the art of plant breeding would understand what a mutant gene is and how to introduce it into a plant (response, page

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2). Applicant cites "Exxon Research and Engineering Co. U.S.265 F. 3d. 1371, 60 USPQ2d 2n (Fed Cir Sept 19<sup>th</sup> 2001) to support this position.

These arguments are not persuasive because claims 15 and 16 as amended do not clearly set forth what Applicant sought for protection. The specification fails to clearly define what is encompassed by "a mutant gene relative to the genes in the plants resulting from growing the seed...of claim 1", and hence one would not know the metes and bounds of the claims. Further, the claims broaden the scope of claims 1 and 2, respectively.

In claim 15, it is unclear whether the claim is drawn to a hybrid plant produced by crossing the plant of claim 2 with another corn plant having a mutant gene, or drawn to the plant of claim 2 further comprising a mutant gene. In claim 16, a seed cannot be crossed to a plant. The Examiner notes that the cited case law has incorrect citation, and therefore, has not been considered. The rejection is maintained.

Claims 10 and 11 are indefinite because "the regenerable cells" lacks antecedent basis, as stated in the Office action of 01/02/03. Applicant has neither amended the claims nor argued against the rejection.

Claims 14 and 17 are indefinite in the recitation of "a transgene capable of being identified", as stated in the last Office action. The phrase is not defined in the specification, and is not known in the art. Are there transgenes not capable of being identified? If so, in what circumstances? Applicant has neither amended the claims nor argued against the rejection. The rejection is maintained.

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Claim 19 is indefinite in the recitation of "biotechnology techniques wherein identifying with genotyping that the seed is an inbred seed" as it is unclear how the biotechnological techniques of screening plant material relates to "identifying with genotyping". Is "identifying with genotyping" intended as separate step or a substep of the "screening"? The claim recites, "further comprising the additional step of screening", however, it appears that multiple steps are involved. Appropriate correction to more clearly define the metes and bounds of the claim is required.

***Claim Rejections - 35 USC § 112, 1st paragraph, deposit requirement***

Claims 1-20 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is repeated for the reasons of record as set forth in the Office action of 01/02/03. Applicant's arguments filed 04/09/03 have been considered but are not deemed persuasive.

Applicant requests that the rejection be withhold until allowable claims are indicated. However, it is noted that the deposit statement on page 29 of the specification does not indicate the viability test of the biological material at the time of the deposit, as required by 37 CFR 1.807. The deposit requirement will be held in abeyance, upon receipt of the written assurance that the viability of the seed will be tested at the time of deposit.

***Claim Rejections - 35 USC § 112, 1st paragraph, enablement***

Claims 12-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is repeated for the reasons of record as set forth in the Office action of 01/02/03. Applicant's arguments filed 04/09/03 have been considered but are not deemed persuasive.

Applicant argues that the claimed invention is enabled, given the teachings by instant specification and the state of the art on the transformation of corn. Applicant also argues against the references cited by the Examiner to support unpredictability in the art with respect to transformation of corn with any transgene or mutant gene, and the undue experimentation required by an skilled artisan to practice Applicant's claimed invention. Applicant cites *Adang v. Fischhoff*, 286 F3d 1346 (Fed. Cir. April 10, 2002) to support this position. Applicant also argues that the Examiner ignores the level of skill and the state of the art on the transformation of corn (response pages 3 and 4).

These arguments have been considered but are not found persuasive. Firstly, the Examiner maintains the cited references to support unpredictability in the transformation of a plant with any gene for a desired phenotype (by Napoli et al, allegedly from the dinosaur age) and the transfer of a gene or mutant gene by breeding method (by Hunsperger et al, Kraft et al, and Eshed et al are still applicable in the instantly claimed invention, especially since Applicant has provided evidence to the contrary. Secondly, the rejected claims are not drawn to transformation of Applicant's inbred corn with specific gene or mutant gene that is known in the art and the resultant

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transformed plant/seed, but encompass transfer of any gene or any mutant gene by introgression or backcrossing from the genetic background of any corn plant to the genetic background of the claimed cultivar plant and hybrid plants thereof. The instant specification fails to provide guidance for the introgression or transfer of a gene by backcrossing without disrupting the expression of the remaining traits whose combination confers patentability to the instantly exemplified variety. Neither the prior art nor Applicant's response provides evidence that such practice is routine in the art. Applicant has not provided a single publication or art to support the asserted predictability in introgression of a mutant gene by backcrossing. Since Applicant has not demonstrated via working examples that a single gene can be transferred from the genetic background of an elite into the genetic background of a plant of the inbred line G3001 while retaining the unique genotypic and phenotypic characteristics of the inbred, and since the prior art does not this deficiency, one skilled in the art who is willing to practice the claimed invention is left with trial and error experimentation considered undue.

With respect to claims 18 and 19, the specification is not enabling for a method of identifying the seed of the inbred line G3001 because the specification does not disclose a repeatable process which would enable a person skilled in the art to reproduce the exact same seed of claim 1, as stated in the Office action of 1/02/03. This is exactly why the deposit of the seed is required.

Therefore, in view of the reasons discussed above and in the Office action of 01/02/03, the claimed invention is not enabled.

***Written Description***

Claims 6-17 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Office action mailed 01/02/03.

Applicants' arguments filed 04/09/03 have been fully considered but are not deemed persuasive.

Applicant argues that the claimed invention is adequately described and is in compliance with the current Written Description Requirement. Applicant relies the following points to support this position: 1) the guidelines require that the inventor conveys to others that he or she had possession of the claimed invention. Applicant asserts that he had done so, as previously pointed out that millions of corn plants fitting the claims were in Applicant's possession. 2) One of ordinary skill in the art knows the family tree of numerous lines of corn or means to identify germoplasm.

Examiner maintains that the claimed invention is not adequately described, given the lack of disclosed representative number of species of the genus of the claims, and the lack of written description for the non-G3001 parents involved in the breeding, as stated in the last Office action of 04/09/03. While one having ordinary skill in the art would know method of identifying germplasm, the specification does not describe molecular information of G3001 or markers unique to G3001. Applicant has not described criteria by which one may identify a corn plant as having G3001 ancestor.

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The instant claims do not recite any morphological, physiological limitations that would distinguish the claimed plants and seeds from those of the prior art. With respect to "transgene" or "mutant genes", the claims do not characterize the sequence or identity of the transgenes or recite phenotypic effects in corn plants and seed.

Accordingly, the claimed invention lacks adequate written description as required under the current written description guidelines, as stated in the last Office action

***Claim Rejections - 35 USC § 102/103***

Claims 6-11, 14 and 17 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Buendgen (US 5, 866, 763). The rejection is maintained for the same reasons as set forth in the Office action mailed 01/02/03. Applicant's arguments filed 04/09/03 have been fully considered but are not found persuasive.

Applicant's conclusion that if a material does not have G3001 as an ancestor then it is not claimed, is not persuasive because the means to identify a plant with G3001 ancestor is not provided in the instant specification. The claims do not recite any plant morphological and/or physiological limitations that would distinguish the claimed plants and seeds from the prior art plants and seed. The claims do not characterize the sequence or identity the transgenes or recite phenotypic effects. The rejection is deemed appropriate.

***Remarks***

Claims 1-5, 12-13, 15-16 and 18-20 are deemed free of the prior art of record.

No claim is allowed.

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2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Papers related to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmission 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday-Thursday from 8:30AM to 5:30PM and every other Friday 9:00AM to 5:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

21/07/03  
Mai



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